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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/394,745
Filing Date: September 15, 1999
Appellant(s): FISHER ET AL.

Gautam Prakash
Holly L. Prutz
David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 20, 2007 appealing from the Office action mailed August 16, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The instant application was finally rejected in an Office Action mailed on September 11, 2002, the decision of which was appealed to BPAI in an appeal received on June 20, 2003; and in a reply-Brief received on January 11, 2005. The basis of the rejection for rejections under 35 U.S.C. 101 and 112, first paragraph was affirmed in the Board's decision mailed on November 22, 2005.

Upon said Board's decision, Applicants filed a Request for Continued Examination (RCE) on January 23, 2006.

Subsequent to the filing of said RCE, the claims were twice rejected (Non-Final Rejection followed by a Final rejection), under the same statutes (101 and 112, 1st para).

It should also be noted, as Applicants' also mentioned in their Brief (on page 2, 1st paragraph), *In re Fisher*, 412 F.3d 1356, 76 U.S.P.Q. 2d 1225 (Fed. Cir. 2005) should have a significant bearing on the merits of the present case.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-10 and 12-27 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The Rejection:

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf, also available on MPEP 2107.01(I)(B)):

> "Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being

"wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

> Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. § 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.
>
> "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

[See also the MPEP at §§ 2107 - 2107.02].

The claimed combination of nucleic acids comprised on a substrate or as a microarray is not supported by a substantial utility because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid. The specification states that the nucleic acid of the microarray are ESTs (expressed sequence tags) which have been derived from LIB189 cDNA library, which was prepared from leaf tissue harvested at anthesis from field grown *Zea mays* genotype RX601 plants (pp. 33-39; see also pp. 92, lines 8-14), and thus ***useful for studying the genes that are agronomically significant*** (pp. 33, 1st paragraph and throughout), expression studies (pp. 43), ***detection of polymorphisms*** (pp. 45-49), and for ***numerous other generic genetic engineering usages***.

There is no evidence that LIB189 is a subtractive cDNA library, wherein nucleic acid molecules from maize tissue other than leaf tissues, from developmental stages other than anthesis, and/or from *Zea mays* plants other than genotype RX601 is subtracted (removed) from the library.

In addition, there is no evidence that any of the nucleic acids comprised in the claimed microarray are expressed only at the time of "anthesis," only in leaf tissue, or only in *Zea mays* plant having the RX601 genotype.

Hence, Applicants' asserted utilities are considered to be non substantial because no substantial utility has been established for the claimed subject matter. For example, a microarray comprising ESTs could be used as a research tool and not substantial in it usage for a particular detection. Unless the array, or the probes fixed on the array (i.e., nucleic acids), are specific for a certain disease, condition, or certain agronomically significant traits, the nucleic acids is only useful for conducting further research to find a substantial utility. The need for such research clearly indicates that the nucleic acid is not disclosed as to a currently available or substantial utility. The research contemplated by applicant(s) to utilize the nucleic acids to conduct find agronomically advantageous traits, such as their biological activities, does not constitute a specific and substantial utility. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acids such that another non-asserted utility would be well established for the compounds.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966), wherein the court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35

U.S.C. 101, which requires that an invention must have either an **immediately apparent** or fully disclosed "real world" utility (emphasis added). The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[i]t is **not a reward for the search**, but compensation for its **successful conclusion**. [emphasis added]

These microarray of the instant application fails to have this substantial utility because the probes on the microarray, by their presence or absence, do not provide a real-world applicability to one ordinarily skilled in the art.

The probes (which make up the microarray) as disclosed, do not provide to one of ordinary skill in the art, what their presence or the absence would be useful for. For a probe to have a **substantial or real-world** utility, its presence or absence must relay to the ordinarily skilled artisan a real-world applicable information, such as detection/predisposition of certain conditions (i.e., cancer markers) (emphasis added). A statement indicating that the array of probes has substantial utility because it can, detect polymorphisms would not give an **immediately apparent**, or substantial utility as court has expressed because such apparent utility would not be found without conducting **further research** on each of the claimed polymorphisms (emphasis added). The claimed microarray lacks a substantial utility because the specification of the instant application fails to provide any guidance that the presence/absence of the claimed nucleic acids correlate to some disease, condition, or presence of harmful agents (i.e., bacteria), etc. The instant application simply relies on the fact that the probes have been patentable in the art and since the claimed microarray comprises probes, it must be patentable. Such reasoning is flawed because nucleic acid probes are not patented

solely on their ability to hybridize to their complement. It is the information (a specific benefit, or an immediately applicable benefit) which is gleaned from the hybridization.

While it is true that a probe (which make up the array) would be found to have an immediately apparent utility, **if**, by its over-expression or under-expression, an artisan could derive a useful information (such as diagnostic for conditions). However, the instant specification fails to disclose any of such benefit. The artisan using the microarray of the instant application would not know why the artisan should use the microarray of the claimed probes over other microarray comprising different probes that are isolated from plants, (i.e., maize). Without conducting further research, the artisan would not have any reason, such as an immediately apparent benefit, to use the claimed microarray comprising the recited SEQ ID Numbers.

At best, Applicants have provided a microarray comprising probes isolated plants, wherein, each probe of the microarray would require further research to find its substantial utility. Such would not be demonstrative of a substantial utility for the claimed subject matter.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1356, 76 USPQ2d 1225 (Fed. Cir. 2005). The Fisher court interpreted the above-discussed Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that 101 requires a utility that is both substantial and specific. Id. At 1371, 76 USPQ2d at 1229. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some further date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. At 1373, 76 USPQ2d at 1231.

Accordingly, the claimed subject matter fails to satisfy the utility as required under 35 U.S.C. 101 for the above reasons.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 and 12-27 are rejected under 35 U.S.C. 112, first paragraph based on the reasoning that since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 8-10 and 12-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Rejection:

The specification discloses claimed SEQ ID Nos, which corresponds to the cDNA associated with plants (i.e., *Zea mays*). The claimed SEQ ID Numbers meet the written description

and enablement provisions of 35 USC 112, first paragraph. However, claims 8-10 and 12-27 recite nucleic acid comprising the claimed SEQ ID Numbers. Because it is not apparent from the specification that the claimed SEQ ID Numbers contain a full open reading frame, the claimed nucleic acids of SEQ ID Numbers read on cDNAs of full open reading frame. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of recited SEQ ID Numbers, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107

F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only the recited SEQ ID Numbers but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

(10) Response to Argument

The Claimed Microarray does NOT have Utility:

Appellants contend the rejection of claims 8-10 and 12-27 under 35 U.S.C. 101 for allegedly lacking a patentable utility.

Appellants state that their specification provides a specific, substantial, and credible utility for the claimed microarrays, such as, analyzing biological samples for the presence of maize nucleic acid sequences relating to genes expressed during anthesis **or** for high-throughput monitoring of gene expression of **such** genes (page 6, 3rd paragraph, Brief).

This statement precisely demonstrates that Appellants have **not** arrived at a substantial utility for the claimed microarray.

It is clear from even the above statement that the microarray of the instant invention lacks an immediately applicable utility as the court expressed in *Brenner v. Manson*, 148 USPQ 689 (1966), wherein the court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which requires that an invention must have either an **immediately apparent** or fully disclosed "real world" utility (emphasis added). The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[i]t is **not a reward for the search**, but compensation for its **successful conclusion**. [emphasis added]

Clearly, Appellants' statement clearly conveys to a skilled artisan that there is no identification of which of the SEQ ID Numbers presented in a Markush group containing **hundreds** of SEQ ID Numbers, are actually involved in the process, ***anthesis***. Hence, a skilled practitioner, in order to arrive at an immediately apparent use (i.e., substantial utility) for the array,

must perform **further research and experimentation**, ***prior*** to using the select probes of the SEQ ID Numbers which may, in fact, be capable of arriving at such utility.

It is respectfully submitted that what Appellants have arrived at is a collection of a plurality of nucleic acid fragments, from which a skilled artisan must derive an immediately applicable utility.

With regard to Appellants' statement regarding the utility of high-throughput monitoring of ***such*** genes, it is pointed out that Appellants have not disclosed which of the hundreds of SEQ ID Numbers are actually expressed during the process of anthesis. Hence, ***contrary to Appellants' assertion,*** a skilled artisan would be incapable of using the invention as Appellants' have disclosed, in the asserted process of "high-throughput monitoring of genes expressed during anthesis" without first conducting **further experimentation and research**, the need of which clearly demonstrating that Appellants have not provided an immediately apparent utility of the claimed subject matter.

This issue was precisely addressed in the Board's initial findings, affirming the utility rejection:

> anthesis. There is, however, no evidence on this record that any of these 100 randomly selected nucleic acid molecules are expressed only at the time of "anthesis," only in leaf tissue, or only in a Zea mays plant having the RX601 genotype.

(page 8, BPAI decision rendered on November 22, 2005, herein, "Decision")

With regard to Appellants' statement regarding the use of the subject microarray for the purposes of hybridizing homologues thereon, such uses were already deemed to lack a substantial utility in the previous decision rendered by the Board:

> Appellants also assert (Brief, page 8), "[o]ther uses for the claimed microarrays are as probes for a multitude of biological molecules, such as nucleic acid homologues or transcription factors, or as a means to assay relative binding efficiency of such molecules." There is no evidence on this record that any of the nucleic acid molecules associated with the microarray of claim 11 would be capable of recognizing other "biological molecules." Further, even if they did since the nucleic acid molecules associated with the microarray of claim 11 are uncharacterized but for their sequence, it is unclear from appellants' specification what information would be derived from the binding of such a biological molecule to appellants' uncharacterized nucleic acid molecule. For

(page 14 of Decision).

Therefore, this issue will not be addressed further as being ***Res Judicata*** (MPEP 706.03(w)).

Appellants' again state that, "as previously stated, the claimed microarray contains nucleic acid sequences from maize corresponding to gene expressed during anthesis." (page 7, bottom paragraph, Brief).

While Appellants may be correct in stating that a microarray containing hundreds of ***uncharacterized*** probes may contain at least one nucleic acid which is expressed during anthesis, this clearly evidences that Appellants were ***not*** aware which of the plurality of sequences in the subject microarray, were expressed during anthesis.

If such assertion can merit a substantial utility, why should one stop at the process of anthesis? One could equally state that the same subject microarray contains gene sequences which is differentially expressed when diseased. Certainly, a microarray containing hundreds of sequences, most likely, would contain a gene sequence which may turn out to be differentially expressed when diseased. Analogously, one may simply pool together thousands human gene sequences in an array and assert that said array contains a gene expressed during a medical condition.

What is absolutely clear in the instant case is that there is no **evidence** that a microarray comprising a random collection of nucleic acids made from at least 10% of the recited SEQ ID

Numbers are expressed during anthesis. A skilled artisan employing the subject microarray would not know what the hybridization would reveal unless said artisan first conducts further experimentation so as to determined which of the hundreds of genes are in fact expressed during anthesis.

Appellants state that the Examiner argued that all nucleic acid molecules are expressed during anthesis (page 8, 2nd column, Brief) and that the statement made by the Examiner, "all nucleic acids are expressed at some point" was erroneous.

Appellants state that not every nucleic acid is expressed during anthesis, and second, all nucleic acids are not expressed at some point (page 8, 2nd paragraph, Brief).

Perhaps Appellants' position is correct regarding that not every nucleic acid is expressed at some point. But Appellants' position must go in both directions.

If not every nucleic acid is expressed at some point, and not every nucleic acid is expressed during anthesis, how can one skilled in the art determine which of the SEQ ID Numbers on the subject array is expressed during anthesis prior to first experimenting with the subject microarray?

In other words, if a skilled artisan were to take Appellant's microarray based on their disclosure and use it in a hybridization reaction, and the result shows a plurality of expressed genes, how can said skilled artisan determine which of the genes were expressed during anthesis, ***prior to first conducting further experimentation*** on each of the SEQ ID Numbers so as to determine that a subset of the hundreds of SEQ ID Numbers are implicative of anthesis?

The **plain fact** that there is no such evidence is a clear indication that Appellants have not arrive at an immediately apparent utility for the subject microarray other than providing a plurality of nucleic acids derived from maize.

This issue is also directly related to the very issue determined in In re Fisher, 421 F.3d 1356, 76 USPQ2d 1225 (Fed. Cir. 2005).

The Fisher court held that 101 requires a utility that is both substantial and specific. Id. At 1371, 76 USPQ2d at 1229. The court held that disclosing a substantial utility means "show[ing] that an invention is **useful to the public as disclosed in its current form** [**key word is, "in its current form"**], ***not*** that ***it may be useful*** at some further date **after further research**. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. At 1373, 76 USPQ2d at 1231.

What is interesting is that Appellants on page 8, 2nd paragraph of their Brief, explicitly states that the nucleic acids of the claimed microarray were expressed during anthesis, which is a "particular phenotype, condition or state."

So, while Appellants, on the very same page of the Brief, state that not every nucleic acid is expressed during anthesis, now appear to assert that **each of the 406 genes** recited in claim 8; **2,889 genes** recited in claims 14, 18, 22, 26, and 27 are **all** expressed during anthesis.

But Appellants do not present any evidence that such is the case nor is this assertion made in the specification.

Again, this issue was already clearly noted in Decision:

> **anthesis. There is, however, no evidence on this record that any of these 100 randomly selected nucleic acid molecules are expressed only at the time of "anthesis," only in leaf tissue, or only in a Zea mays plant having the RX601 genotype.**

(page 8, BPAI decision rendered on November 22, 2005)

Appellants state that the Office focused on the utility of the individual nucleic acid sequences contained on the claimed microarray, but contend that claims must be considered as a whole in determining compliance with 101 (page 8, bottom to page 9, 1st paragraph, Brief).

In this contention, Appellants state that they are not claiming nucleic acid sequences in abstract but rather, nucleic acid sequences obtained from maize. Appellants also state that the claims are not limited to the nucleic acid sequences, but are directed as a whole to microarrays that comprise, *inter alia*, various nucleic acid sequences selected from the recited Markush group (page 9, 1st paragraph, Brief).

It is respectfully submitted that Appellants have either misunderstood or mischaracterized the Office' position on utility.

It is clear that the claims are drawn to a collection of nucleic acids (in a microarray format) and the utility of said collection of nucleic acids were determined based on the nucleic acids comprised in said collection. In other words, the claims were not analyzed for their utility based on a single nucleic acid from said Markush group, but rather, analyzed based on whether a collection of SEQ ID Numbers had a substantial utility by determining the utility of the nucleic acids which fall within said collection.

This point was again addressed in the previous Decision:

to the array. In contrast, appellants' claimed invention is directed to a microarray that comprises specific nucleic acid molecules identified by SEQ ID NO. Accord, Supplemental Answer, page 9. Therefore, the question is not whether microarrays are generally useful; to the contrary, the question is whether appellants have satisfied the utility requirement for a very specific microarray that comprises 100 nucleic acid molecules (ESTs) identified by SEQ ID NO., as set forth in appellants' claim 11.

(page 10, 1st paragraph from Decision)

And fully construing the claims ***as a whole***, the Board reached the following conclusion:

the extent that appellants assert that Pirrung and Fodor demonstrate that the specific microarray set forth in appellants' claim 11 is useful, we disagree. In our opinion, the utility of a microarray is dependent on the reagent, in this case the nucleic acid molecules, associated with the microarray. In this regard, appellants assert (First Brief, page 10), the microarray of claim 11 "allow[s] one of ordinary skill in the art to design or customize a particular microarray tailored to the specific requirements of the artisan himself." While this may be true of the microarrays taught by Pirrung and Fodor, it is not true for the microarray set forth in appellants' claim 11. The microarray of appellants' claim 11 requires that the nucleic acid molecules comprise nucleic acid sequences complementary to the recited SEQ ID NOs. Thus, contrary to appellants' assertion, a person of

ordinary skill in the art wishing to use the microarray of appellants' claim 11 is confined to the use of nucleic acid molecules that comprise nucleic acid sequences complementary to the recited SEQ ID NOs. Thus, the utility of the microarray set forth in appellants' claim 11 is dependent on the nucleic acid molecules associated with the microarray, specifically those that comprise nucleic acid sequences complementary to the recited SEQ ID NOs. However, as discussed above, the only information appellants have disclosed about these nucleic acids is their SEQ ID NOs. We also disagree with appellants' assertion

(page 10 to page 11, 1st paragraph, Decision)

Appellants next clearly mischaracterize the Board's statement, taking the statement **out of context**, so as to justify Appellants' position (page 10, 1st and 2nd paragraph, Brief).[1]

For the sake of convenience, the subject statement will be reproduced herein, ***as a whole***:

to any particular nucleic acid molecules. The same is true of the invention set forth in Pirrung's claims. Thus, in each of Fodor and Pirrung, the skilled artisan is free to select the relevant reagent (e.g., nucleic acid) of their choice to attach to the array. In contrast, appellants' claimed invention is directed to a microarray that comprises specific nucleic acid molecules identified by SEQ ID NO. Accord, Supplemental Answer, page 9. Therefore, the question is not whether microarrays are generally useful; to the contrary, the question is whether appellants have satisfied the utility requirement for a very specific microarray that comprises 100 nucleic acid molecules (ESTs) identified by SEQ ID NO., as set

[1] Appellants state that the Office has acknowledged that microarrays in general have a specific and substantial utility by way of their utility for being able to analyze a plurality of nucleic acid samples simultaneously, but fails to address how the Board stated that Appellants' claimed invention does NOT have a substantial utility for reasons following said statement.

What the Board was expressing was in that the patentable utility of Fodor and Pirrung had a substantially utility in that the microarray was capable of analyzing a plurality of nucleic acids simultaneously, wherein the claims of Fodor and Pirrung's patentable utility did not rest on the SEQ ID Numbers.

> general may have utility as demonstrated by Pirrung and Fodor, we agree. To the extent that appellants assert that Pirrung and Fodor demonstrate that the specific microarray set forth in appellants' claim 11 is useful, we disagree. In our opinion, the utility of a microarray is dependent on the reagent, in this case the nucleic acid molecules, associated with the microarray. In this regard, appellants assert (First Brief, page 10), the microarray of claim 11 "allow[s] one of ordinary skill in the art to design or customize a particular microarray tailored to the specific requirements of the artisan himself." While this may be true of the microarrays taught by Pirrung and Fodor, it is not true for the microarray set forth in appellants' claim 11. The microarray of appellants' claim 11 requires that the nucleic acid molecules comprise nucleic acid sequences complementary to the recited SEQ ID NOs. Thus, contrary to appellants' assertion, a person of

(page 10, bottom paragraph, Decision).

Clearly, Appellants' arguments produced on pages 10-12 of instant Brief are a reiteration of the arguments which were presented before the Board, wherein the Board having considered the arguments, established their decision, expressing that the claims had no patentably utility.

Claimed Microarrays are NOT enabled by the specification

Appellants' arguments in the present section are dependent on whether or not a patentable utility for the claimed subject matter has been satisfied.

As fully discussed above, the instant application fails to disclose a substantial utility for the claimed subject matter, and thus, one of skill in the art would not be able to practice the invention (i.e, how to use the invention) without undue experimentation.

The claimed subject matter does NOT satisfy the written description requirement

Appellants state that the claimed microarrays do not recite open reading frames, and thus need not describe them (page 14, bottom paragraph, Brief) and that moreover, the skilled artisan would be able to identify open reading frames within the recited sequences using methods known in the art, concluding that Appellants have fully described each SEQ ID Numbers by setting forth its nucleotide sequence.

Initially, whether or not the claims actually claim a full open reading frame is irrelevant to establishing the breadth of the claims. If such an explicit recitation was required for a patent claims, then a claim drawn to an isolated polynucleotide comprising SEQ ID Number 1, wherein the specification only discloses a partial open reading frame would not embrace an isolated polynucleotide containing a full open reading frame. Clearly, such is not so.

Secondly, whether one of skill in the art can isolate the full open reading frame or not is not a proper demonstration of possession.

In University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405, the court, citing *Fiers v. Revel* (984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), expressed that "[a]n adequate written description of a DNA, such as the cDNA of the recombinant plasmids and

microorganisms of the '525 patent, 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' ***not a mere wish to plan*** for obtaining the claimed chemical invention."

What is even more interesting is that in *Lilly*, the specification (U.S. Patent No. 4,652,525) disclosed an explicit example of producing cDNA from pancreas of rats (see column 15, line 39-40 and through column 17, line 36). The specification also gave guidance drawn to generating cDNA of **human** insulin (column 19, line 50 through column 20, line 14), wherein the specification **even disclosed the amino acid sequences** encoding **human** insulin A (column 19, lines 64-65) ***and*** the ***amino acid sequences encoding human insulin B*** (column 20, lines 5-10).

However, the court deemed that claims drawn to cDNA encoding human insulin were not described. While one of skill in the art would have been able to derive every possible nucleic acid sequence encoding the insulin based on codon degeneracy (every possible nucleic acid sequence which must, undoubtedly include that which is of human), based on the disclosed amino acid sequence of human insulin, the **court required the actual "DNA itself."** (at 1405) expressing that description cannot be established based on a "mere statement that it is part of the invention and reference to a potential method for isolating it."

Hence, Appellants' disclosure of obtaining a nucleic acid comprising a full open reading frame by use of the claimed microarray comprising fragments of a full open reading frame, cannot serve to satisfy the requirement under written description.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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